



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Girish J. KOTWAL et al.

Application No.: 09/889,624

Filing Date: November 7, 2001

Title: APPLICATION OF A VIRAL COMPLEMENT INHIBITORY PROTEIN IN THE TREATMENT AND DIAGNOSIS OF ALZHEIMER'S DISEASE

Group Art Unit: 1646

Examiner: Joseph F. Murphy

Confirmation No.: 6917

AMENDMENT/REPLY TRANSMITTAL LETTER

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Enclosed is a reply for the above-identified patent application.

- ☐ A Petition for Extension of Time is also enclosed.
- ☐ Terminal Disclaimer(s) and the ☐ \$55.00 (2814) ☐ \$110.00 (1814) fee per Disclaimer due under 37 C.F.R. § 1.20(d) are also enclosed.
- ☐ Also enclosed is/are \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_
- ☐ Small entity status is hereby claimed.
- ☐ Applicant(s) requests continued examination under 37 C.F.R. § 1.114 and enclose the ☐ \$385.00 (2801) ☐ \$770.00 (1801) fee due under 37 C.F.R. § 1.17(e).
- ☐ Applicant(s) requests that any previously unentered after final amendments not be entered. Continued examination is requested based on the enclosed documents identified above.
- ☐ Applicant(s) previously submitted \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_ on \_\_\_\_\_,  
for which continued examination is requested.
- ☐ Applicant(s) requests suspension of action by the Office until at least \_\_\_\_\_, which does not exceed three months from the filing of this RCE, in accordance with 37 C.F.R. § 1.103(c). The required fee under 37 C.F.R. § 1.17(i) is enclosed.
- ☐ A Request for Entry and Consideration of Submission under 37 C.F.R. § 1.129(a) (1809/2809) is also enclosed.

- ☒ No additional claim fee is required.
- ☐ An additional claim fee is required, and is calculated as shown below.

AMENDED CLAIMS					
	No. of Claims	Highest No. of Claims Previously Paid For	Extra Claims	Rate	Additional Fee
Total Claims		MINUS 20 =	0	x \$18.00 (1202) =	\$ 0.00
Independent Claims		MINUS 3 =	0	x \$86.00 (1201) =	\$ 0.00
If Amendment adds multiple dependent claims, add \$290.00 (1203)					
Total Claim Amendment Fee					\$ 0.00
<input type="checkbox"/> Small Entity Status claimed - subtract 50% of Total Claim Amendment Fee					\$ 0.00
<b>TOTAL ADDITIONAL CLAIM FEE DUE FOR THIS AMENDMENT</b>					<b>\$ 0.00</b>

- ☐ A check in the amount of \_\_\_\_\_ is enclosed for the fee due.
- ☐ Charge \_\_\_\_\_ to Deposit Account No. 02-4800.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17, 1.20(d) and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

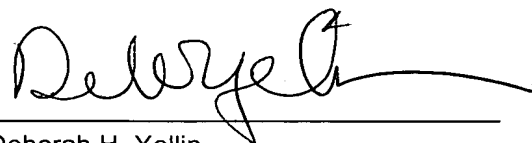
Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

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Alexandria, Virginia 22313-1404  
(703) 836-6620

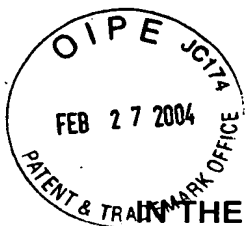
Date: February 27, 2004

By



Deborah H. Yellin

Registration No. 40,904



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	)	
Girish J. KOTWAL et al.	)	Group Art Unit: 1646
Application No.: 09/889,624	)	Examiner: Joseph F. Murphy
Filed: November 7, 2001	)	Confirmation No.: 6917
For: APPLICATION OF A VIRAL	)	
COMPLEMENT INHIBITORY	)	
PROTEIN IN THE TREATMENT	)	
AND DIAGNOSIS OF ALZHEIMER'S	)	
DISEASE	)	

**RESPONSE TO RESTRICTION REQUIREMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In complete response to the Requirement for Restriction issued by the Patent and Trademark Office on January 29, 2004, applicants hereby elect with traverse the invention of Group I, claims 1-6, for prosecution in this application. Group I is directed to a method of treatment of Alzheimer's disease with a protein of SEQ ID NO: 1. Applicants respectfully reserve the right to pursue any non-elected subject matter in a divisional or continuation application, if it is not rejoined to the subject matter elected herein.

37 C.F.R. § 1.475 and M.P.E.P. § 1893.03(d) indicate that when a group of inventions is claimed in a national stage application (filed under 35 U.S.C. § 371) unity of invention is fulfilled when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. Thus, even if a group of inventions is claimed, a restriction for lack of unity should not be made unless the claims lack the same or corresponding special technical features.

Group I relates to a method of treatment of Alzheimer's disease with a protein of SEQ ID NO: 1. Group II is directed to a pharmaceutical composition comprising SEQ ID NO: 1. Group III is drawn to a method of detecting amyloid plaques with a labeled protein with the amino acid sequence of SEQ ID NO: 1. These claims are thus all united by the underlying principle of the use of SEQ ID NO: 1 in the treatment and diagnosis of Alzheimer's disease. Unity of invention thus exists.

Furthermore, Applicants note that the Examiner of the corresponding PCT international application did not determine that the claims lacked unity. In fact, the Examiner searched and examined all of the claims together in the PCT international application. The claims of the PCT application cover the same subject matter as those in the current U.S. national stage application, albeit the claims in the current application were amended to conform to U.S. claim format. To now require that the claims lack unity would contradict what was done in the corresponding international PCT application.

It is well established that if the rule and interpretation of the PTO with regards to unity of invention conflicts with the PCT, it runs afoul of Article 27 of the PCT. *Caterpillar Tractor Co. v. Commissioner of Patents and Trademarks*, 231 U.S.P.Q. 590 (E.D. Va. 1986). Article 27 of the PCT provides in part that "no national law shall require compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in this Treaty and the Regulations." *Caterpillar Tractor*, 231 U.S.P.Q. at 591. Therefore, a restriction requirement based on a lack of unity would be improper.

In the event that there are any questions relating to this amendment or the application in general, it would be appreciated if the Examiner would contact the undersigned attorney at (703) 836-6620

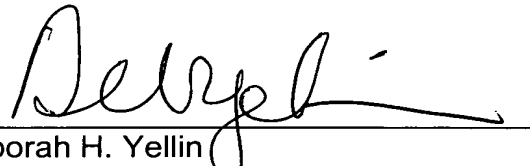
Early and favorable action in the form of a notice of allowance is respectfully requested.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: February 27, 2004

By: \_\_\_\_\_

A handwritten signature in dark ink, appearing to read "Deborah H. Yellin", written over a horizontal line.

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